Part of Paper #4
09/177,502

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Slater	
v.	INTERFERENCE NO. 103,765
Rydell	Administrative Patent Judge Pate

DECLARATION OF DAVID J. PARINS

I, David J. Parins, declare and say as follows:

1. Attached hereto as Exhibit 1 is a current copy of my Curriculum Vitae. As is reflected therein, between November 1988 and October 1997, I was continuously employed by Everest Medical Corporation, the assignee of the invention described and claimed in U.S. Patent Application 08/724,997, which is involved in the above-captioned Interference. In my position as Director-Product Development and Director-Business Development, I kept aware of new product concepts being worked on within the company. In the period from 1988 to the present, Everest Medical Corporation has been located in a single, one-story building, and at all times, I have had access to the research, development, engineering and production areas of the company. As such, I have had the opportunity to interact with personnel engaged in the design, development and testing of potential new products.

2. Between 1988 and the present, Everest Medical Corporation has been continuously involved in the design and development of a wide variety of electrosurgical instruments,

including scissors, forceps, scalpels, snares, ablation catheters, biopsy instruments, etc. Everest Medical Corporation has directed most of its attention to developing instruments involving bipolar technology, so that electrosurgical current paths would be confined between closely-spaced electrodes.

3. In the period from November 1988, until a time in 1993 when he terminated his employment, I was a co-worker of Mark A. Rydell at Everest Medical Corporation. Even following his termination as an employee, I have maintained a close association with Mr. Rydell in that he continues to serve as a paid consultant to Everest Medical Corporation.

4. I have read Mr. Rydell's Declaration dated 9/30, 1998, submitted in the present Interference to prove conception and reduction to practice of a particular bipolar scissors and I can corroborate the facts recited in paragraph 1-4, 6, 7, and 11 thereof. I personally recall seeing and actually using the electrosurgical scissors constructed by Mark Rydell and depicted in the photographs of Exhibit F to the Rydell Declaration. I used that scissors to cut and desiccate raw meat in a laboratory facility at Everest Medical Corporation in December 1991. Although I did not personally participate in the testing of the scissors depicted in the photos of Exhibit F to the Rydell Declaration in the animal lab at the University of Minnesota, which is recited in paragraphs 8 and 9 of the Rydell Declaration, I was apprised of the conclusions reached by Mr. Rydell and Mr. Joseph A. O'Brien, that the hook scissors in question did, in

fact, cut a variety of tissue types and that it was effective to coagulate bleeding from severed blood vessels to effect hemostasis, and that it would be necessary to do further work on the scissors to improve its ability to mechanically cut certain tissue types before it could be successfully marketed. I attended a Product Development staff meeting held on December 23, 1991, and recall the discussion at that meeting of the results of the testing that took place on December 19, 1991, at the University of Minnesota Medical School. Attached hereto as Exhibit 2 is a Memo from Joseph O'Brien, summarizing the December 23, 1991 meeting. I am the "Dave P." listed therein as a recipient of the memo. A copy of this memo has been retained in the files of Everest Medical Corporation in its ordinary course of business.

5. Throughout the period from December 1991 to the present, Everest Medical Corporation has continued to design, develop and make improvements to its line of bipolar electrosurgical scissors. In the fall of 1992, it first began sales of the EVERSHEARS® electrosurgical scissors. It comprised an elongated tubular barrel having a scissors handle affixed to one end and a blade assembly connected to its opposite end. The blades comprised flat ceramic pieces defining its cutting edge and shearing surfaces and the electrocautery voltage was applied between metal blade support members on which the ceramic pieces were mounted. This product was marketed for about 18 months, with approximately 4,000 units being sold. Attached as Exhibit 3

is a page from the Everest Medical Corporation 1992 Annual Report to Stockholders confirming the introduction of the EVERSHEARS® bipolar scissors in November 1992. During that period, work was going forward on the development of a bipolar electrosurgical scissors having curved ceramic blades. The scissors with the curved ceramic blades was introduced in the fall of 1993 and about 10,000 such scissors were sold. Exhibit 4 is a page from the Everest Medical Corporation Annual Report for 1993 confirming the introduction of its curved ceramic scissors.

Everest Medical Corporation experienced some difficulty with the curved ceramic scissors. About 1 out of 1,000 would fail during use because the curved ceramic coupon would separate from its metal blade support. It proved fortunate that the company had continued the development of its metal-on-metal scissors blades for it was at this point that the company completed development and began producing the EVERSHEARS II® bipolar scissors that is described in the Rydell U.S. Patent 5,352,222, a copy of which is attached as Exhibit 5. The cooperating blades each were constructed as a laminated assembly of a conductive metal electrode separated from a conductive metal blade element that defined its cutting edge and shearing surface by a layer of insulation. In these regards, the blade members of the EVERSHEARS II® product were the same as on the hook scissors built by Mark Rydell in December 1991 and tested in a surgical procedure on a live animal on December 19, 1991. The metal-on-metal curved EVERSHEARS II® scissors was introduced in about

September 1994 and first sales thereof took place in January 1995. Attached as Exhibit 6 are pages from the Company's 1994 Annual Report confirming these events.

6. Based upon my knowledge of the efforts made by Everest Medical Corporation in the period 1990-present to develop bipolar laparoscopic electrosurgical scissors that would permit both mechanical cutting and electrocoagulation without the need for an instrument exchange, the Company had no intent to either abandon, suppress or conceal the hook scissors invention which Mark Rydell designed, built and tested in December 1991. To the best of my knowledge and belief, Everest Medical Corporation was the first to introduce a product embodying the metal-on-metal blade design on an electrosurgical scissors to the marketplace and was the first to disclose the invention in a patent application.

7. I hereby state that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above application or any patent issuing thereon.

Further affiant saith not.

Dated: 9/22, 1998.

David J. Parins

David J. Parins

Exhibit 1

David J. Parins
6801 Olde Sturbridge
Corcoran, MN. 55340
(612) 478-9793

5-98 - Present **Everest Medical Inc.**, Minneapolis, MN.
(An Electrosurgical Endoscopic Instrument Manufacturer)
Vice-President Technology

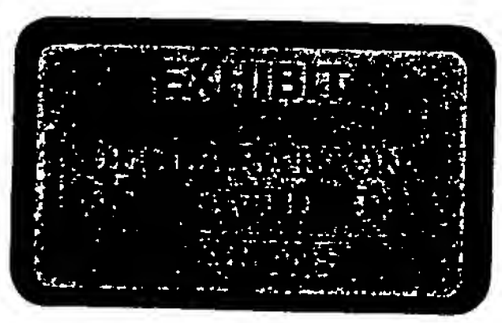
9-97 - 5-98 **Cardiac Instruments Inc.**, Minneapolis, MN.
(A Cardiovascular Device Manufacturer)
Vice-President of Research and Development

11-88 - 9-97 **Everest Medical Inc.**, Minneapolis, MN.
(An Electrosurgical Endoscopic Instrument Manufacturer)
Vice-President of Engineering, Quality, and Regulatory Affairs
Vice-President of Business Development and Regulatory Affairs
Director Business Development
Director Product Development

9/83 - 11/88 **Schneider (USA) Inc.**(Formerly Angiomedics Inc.)
(A Div. of Boston Scientific)Minneapolis, MN.
(An Interventional and Diagnostic Catheter Manufacturer)
Product Manager Radiology
Principal Engineer - Business Development
Director of Research
Manager of Catheter Development

9/75 - 9/83 **Cardiac Pacemakers Inc.**, St. Paul, MN. (Guidant Corp.)
(An Implantable Cardiac Device Manufacturer)
Manager - Leads and Sensor Technology
Biomaterials Research Engineer
Manufacturing Engineer

EDUCATION 9/69 - 6/74 **Marquette University,** Milwaukee, WI
B.S. Major: Mechanical Engineering



Patents

Cardiac Pacer Electrode and Lead Insertion Tool - No, 4,146,037

Angioplasty Catheter Assembly - No. 4,646,742

Bipolar scalpel for harvesting internal mammary artery - No. 5,013,312

Ablation catheter with selectively deployable electrodes - No. 4,976,711

Ablation catheter with selectively deployable electrodes - No. 5,057,107

Percutaneous laparoscopic cholecystectomy instrument - No. 5,171,311

Percutaneous laparoscopic cholecystectomy instrument- No. 5,071,419

Ablation catheter with selectively deployable electrodes
No. 5,078,717

Electrosurgical instrument for ablating endocardial tissue No. 5,083,565

Ablation catheter with selectively deployable electrodes No. 5,125,928

Bipolar instrument utilizing one stationary and one movable electrode No. 5,197,964

Pivoting multiple loop bipolar cutting device No. 5,192,280

Electrosurgical instrument with extendible, sheath for irrigation and aspiration - No. 5,197,963

Bipolar biopsy device utilizing a rotatable, single-hinged moving element
No. 5,217,458

Bipolar sphincterotome utilizing side by side parallel wires No. 5,201,732

Bipolar instrument utilizing one stationary electrode and one movable electrode
No.5,290,286

Bipolar electrical scissors with metal cutting edges and shearing surfaces
No.5,540,685

Endoscopic Bipolar Biopsy Forceps No.5,603,711

Endoscopic Bipolar Biopsy Forceps No.5,743,906

PUBLICATIONS

1. **"Interactions of blood with solid and porous endocardial electrodes for cardiac pacemakers,"** Clawson, C.C., Parins, D.J., White, J.G., and MacCarter, D.J. Scanning Electron Microscopy 1980, III.

2. **"In Vivo Degradation of a Polyurethane",** Parins, D.J., Black, K., McCoy, K., Horvath, N.J., Cardiac Pacemakers, Inc. 2-81

3. **In Vivo Degradation of Polyurethane : Further evidence.** Parins, D.J., McCoy, K.D., and Horvath, N.J.: PACE, 5:302, 1982 (Abstract).

4. **Failure Mechanisms in Polyurethane Leads.** Parins, D.J. RBM (European Review of Biomedical Technology) Vol. 4, No 5, September-October 1982. p. 390. Presented at Cardiostim 82, Paris, France, October 9, 1982.

5. **In Vivo Degradation of a Polyurethane: Pre clinical Studies,** Parins, D.J., McCoy, K.D., Horvath, N.J., and Olson, R.W., Corrosion and Degradation of Implant Materials. Second Symposium, ASTM STP 859, A.C. Fraker and C.D. Griffin Eds. 1985, p.p. 322-339.

Exhibit 2

Everest Medical

INTEROFFICE MEMO

TO: Mike H, Steve H, Mark R, Jerry S, Dave P, Greg G, Brent A, Kevin R

FROM: Joe O'B

SUBJECT: Product Development Meeting 12/23

The following list of development priorities was reviewed and agreed upon. It will be posted and included in the weekly product development meeting notes.

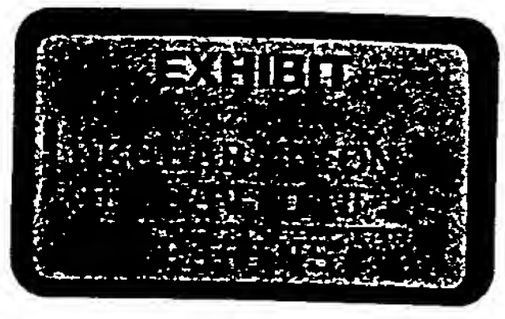
NEW PRODUCTS PRIORITIES

1. Bipolar Laparoscopic Scissors
2. Bipolar Laparoscopic Forceps
3. Suction/Irrigation Handle for BiLAP
4. Reusable BiLAP with interchangeable tips
5. Adapter box for competitive generators
6. Traditional design endoscopic biopsy device
7. Fulgurating Snare
8. Monopolar Snare

PRODUCT MODIFICATION PRIORITIES

5128

1. BiLAP modifications: ceramic tip / detent / stiffer tubing / non-stick coating
2. Model 5126 BiSNARE
3. Hand switching straight tip BiLAP
4. BiLAP modifications: Steam autoclavable / 4.8 mm
5. BiTOME



6. ERCP

7. Non-Stick coating for BiCOAG PROBE

8. BiBx

Bipolar Laparoscopic Scissors:

- Marketing specification completed

- Reviewed GANTT chart prior to meeting (Mark, Greg, Joe) and will revise and distribute. Product introduction is scheduled for April 10th.

- Joe will review revised GANTT chart with Manufacturing by end of week.

- Results of dog lab were reviewed. Good coagulation but poor mechanical cut.

- Mark will have new prototype as well as blade and handle drawings by Jan. 7.

- Dog lab should be scheduled to test new prototype.

Bipolar Laparoscopic Forceps:

- Marketing Specification completed

- Reviewed GANTT chart prior to meeting (Mark, Greg, Joe) and will revise and distribute. Product introduction scheduled for April 10th.

- Joe will review revised GANTT chart with manufacturing this week.

- Memo describing uses to date has been distributed.

- Mark is building a second unit. More uses will be scheduled.

BiLAP Modifications: Ceramic Tip / Detent / Stiffer Tubing / Coating:

- Ceramic tips will be in house on Jan. 16th.

- According to Greg, stiffer tubing was improperly processed by Jerneen. New tubing will be in house next week. Some testing can start on the tubing we have.

- Detent; ten devices will be built by next week.

- Coating; two coatings have been initially evaluated with unspectacular results. Greg will evaluate 3M, Videx and gold for their potential.

Suction / Irrigation Handle:

- Kevin needs to complete marketing spec immediately. In connection with the marketing spec., Kevin should discuss prototype and GANTT chart with Design.

- Steve will follow up w/ Kevin on potential outside design.

- Corey will begin drawing potential designs.

Hand switching straight tip:

- Kevin needs to develop or revise a marketing spec. and GANTT chart for the hand switching straight tip.

- Kevin and Steve need to address the need for hand switching J, L and H per design request.

Adapter Box:

- Greg said that the first box will be here Thursday 12/26. The box needs to be tested as soon as possible.

Miscellaneous:

- Marketing will get access to an Olympus video system to evaluate interference with our monopolar generator.

- Joe will submit second communication re. Japanese special BiTOME's.

Exhibit 3

EVEREST MEDICAL

TO OUR SHAREHOLDERS

Our Company has made good progress in penetrating the laparoscopic surgical market, with total sales of almost $2.2 million in 1992. This 75% growth in revenue was achieved primarily through the introduction of new products in the laparoscopic surgical markets. Our GI endoscopy sales also increased compared to the previous year. Losses were greater than last year, primarily due to the difficulties of establishing a base of sales. The resulting low manufacturing volumes led to poor margins.

By year end, we began to achieve measurable success in the gynecology market and our new bipolar forceps and scissors were being well received in the United States. With only limited resources available for training surgeons on the advantages of bipolar electrosurgery, we directed most of our selling efforts in the gynecology market where the surgeons are more experienced in minimally invasive surgery and are already aware of the merits of bipolar technology.

We made good progress in strengthening our distribution. We achieved significant revenue from our private label supply relationship with C.R. Bard, Inc. and in the forth quarter commenced shipment of product under two additional corporate relationships. We started selling a modified BiLAP device to European accounts through ERBE Elektromedizin GmbH of Germany, believed to be the largest electrosurgical company in Europe. Under this relationship, Everest Medical manufactures the critical components while ERBE completes final assembly and packaging.

We also secured an agreement with Origin Medsystems, Inc., a division of Eli Lilly. Through Origin we are selling a private label bipolar forceps, and we are developing additional products for them that are expected to be released in 1993.

Our own distribution improved in the United States as we added several independent stocking distributors who are beginning to achieve success with our product. We also expanded our efforts to secure independent comissioned sales people for selected territories, a mode which will provide us with better control in these markets and will improve our margins.

1992

Product development efforts were very successful in 1993. The release of our BiCOAG Bipolar Forceps in late September and the release of our EVERSHEARS Bipolar Scissors in late November was successful. We anticipate strong sales from each of these product lines in 1993.

In the fourth quarter we added two new board members who have provided considerable strategic assistance. Judy Lindstrom of MicroAire Surgical and Richard Nikolaev of Orthomet, Inc. both have years of experience in the surgical device marketplace and are a welcome addition to the board.

As we close the year we are optimistic about the future of our company and the more general acceptance or our bipolar technology, but we must improve our operating results through improved sales. We are seeking additional corporate relationships that will provide us with good margins while improving the market penetration of our products and technology. We are also pursuing the additional capital resources which will be required.

Thank you for your continued support.

Michael J. Hollenhorst
Chairman and Chief Executive Officer

EXHIBIT
DECLARATION OF DAVID J. BARINS

Exhibit 4

Superiority of Bipolar Technology

The majority of general surgeons currently utilize monopolar electrosurgery. The use of monopolar technology increases the risk of patient injuries due to unintended thermal injury and lateral tissue damage. Inherently safer, bipolar electrosurgery is gaining recognition and acceptance in this market. For years, many gynecologic surgeons have understood the benefit of bipolar electrosurgical instrumentation for their patients. Bipolar technology offers the physician more control and less tissue damage with effective hemostasis and uncompromised performance. The use of bipolar electrosurgery eliminates the potential of injury due to grounding pad burns. Bipolar technology allows the surgeon the use of electrosurgery in procedures previously avoided due to the concern of patient injury resulting from monopolar energy. In these complex procedures, the use of bipolar electrosurgery may save surgical time, as well as the expense associated with sealing vessels mechanically.

In April 1993, *The BBI Newsletter* estimated that by 1997 bipolar electrocautery probes would capture 50% of the overall surgical instrument market. This estimate was based on market research stating that 47% of surveyed laparoscopic surgeons felt "the dangers [of monopolar energy] were real." The interest in bipolar electrosurgical instrumentation continues to build as evidenced by the Company's recent strategic partnerships and continued sales growth. The Company believes that as MIS evolves into more sophisticated and complex procedures, the need for bipolar electrosurgery becomes even more evident.

Leading Edge New Product

In the fall of 1993, the Company introduced a curved version of its EVERSHEARS Bipolar Scissors. At this time, the Company believes that this product continues to be the first and only single-use bipolar scissors currently available for general sale throughout the world. EVERSHEARS Bipolar Scissors offer precision cutting with the safety of bipolar coagulation. The Company believes that the curved version of this product will greatly assist efforts to significantly increase market share. Dependent on the specific procedure, the use of this product may reduce surgical time and costs, and may be a cost-effective alternative for mechanical sealing of vessels with improved safety for patients. The gynecology community has responded with great interest for this product, and we have begun to make solid inroads into the general surgery market as well.

The Company currently has four pending patents on its laparoscopic bipolar scissors technology. We are aware of a competing patent pending which may be issued prior to the Company's initial patent. Although the Company has concerns regarding this patent situation and its potential effect on our business, we believe that our technical and manufacturing expertise will allow Everest to be a factor in the bipolar scissors market in the future.

Partners in Health Care Excellence

Everest Medical continues to strengthen its domestic sales force of distributors and manufacturers' representatives. The Company currently has over 60 independent sales professionals representing Everest-branded bipolar products to the medical community with a primary emphasis on gynecological laparoscopy.

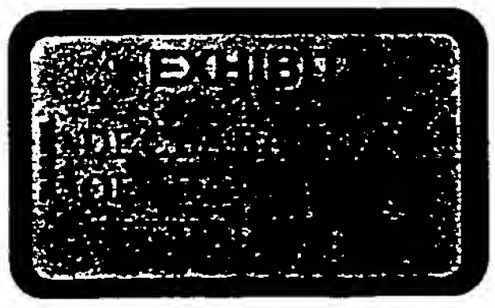


Exhibit 5

US005352222A

United States Patent [19]

Rydell

[11] Patent Number: 5,352,222

[45] Date of Patent: Oct. 4, 1994

[54] SURGICAL SCISSORS WITH BIPOLAR COAGULATION FEATURE

[75] Inventor: Mark A. Rydell, Golden Valley, Minn.

[73] Assignee: Everest Medical Corporation, Minneapolis, Minn.

[21] Appl. No.: 213,671

[22] Filed: Mar. 15, 1994

[51] Int. Cl.[5] A61B 17/39

[52] U.S. Cl. 606/37; 606/45; 606/52; 606/170; 606/174

[58] Field of Search 606/27, 29, 32, 34, 606/37, 39, 40, 41, 45, 46, 47, 48, 49, 50, 51, 52, 167, 170, 171, 174, 175

[56] References Cited

U.S. PATENT DOCUMENTS

5,147,356	9/1992	Bhatta	606/37
5,312,434	5/1994	Crainich	606/45 X

FOREIGN PATENT DOCUMENTS

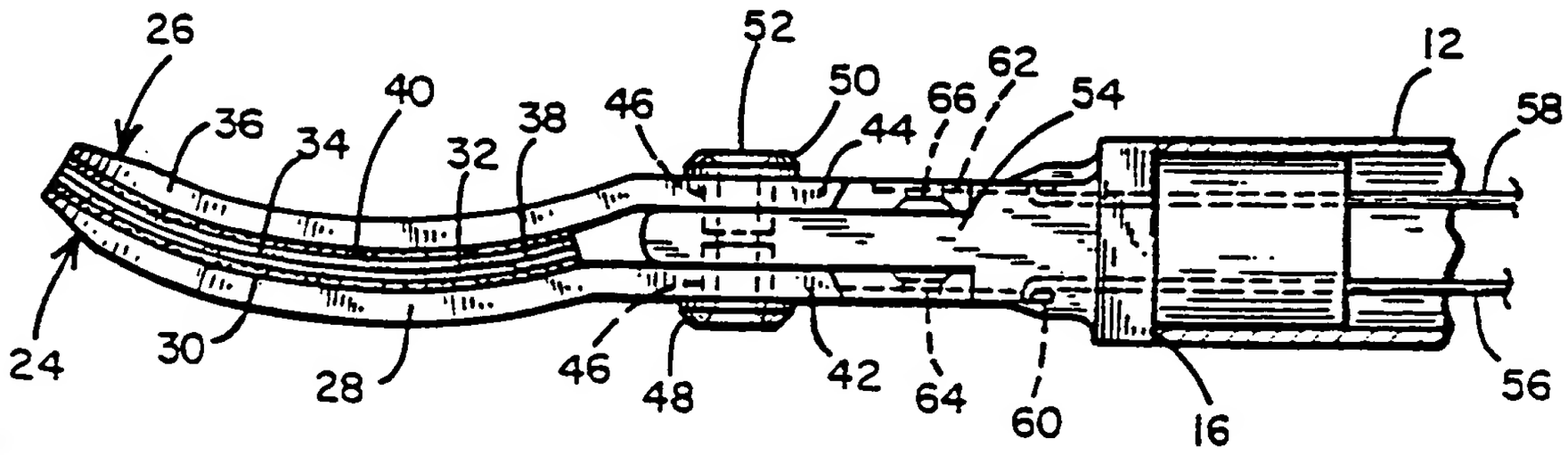
517244	12/1992	European Pat. Off.	606/37
518230	12/1992	European Pat. Off.	606/37

Primary Examiner—Peter A. Aschenbrenner
Attorney, Agent, or Firm—Haugen and Nikolai

[57] ABSTRACT

A bipolar electrosurgical scissors for use in open or endoscopic surgery has a pair of opposed blade members pivotally joined to one another and to the distal end of the scissors itself by a rivet which extends through a insulated bushing member. Each of the blade members comprises a blade support and a blade itself, each fabricated from metal, such as stainless steel. The blades are affixed to their associated supports by means of a suitable adhesive or adhesive composite material such as a fiberglass reinforced epoxy exhibiting dielectric properties. Cutting is performed, steel-on-steel, without causing a short circuit between the two blade supports which themselves function as the bipolar electrodes.

11 Claims, 1 Drawing Sheet



ance fees
s and six
fter upon
g of the
nt of the
efore the
pire as of

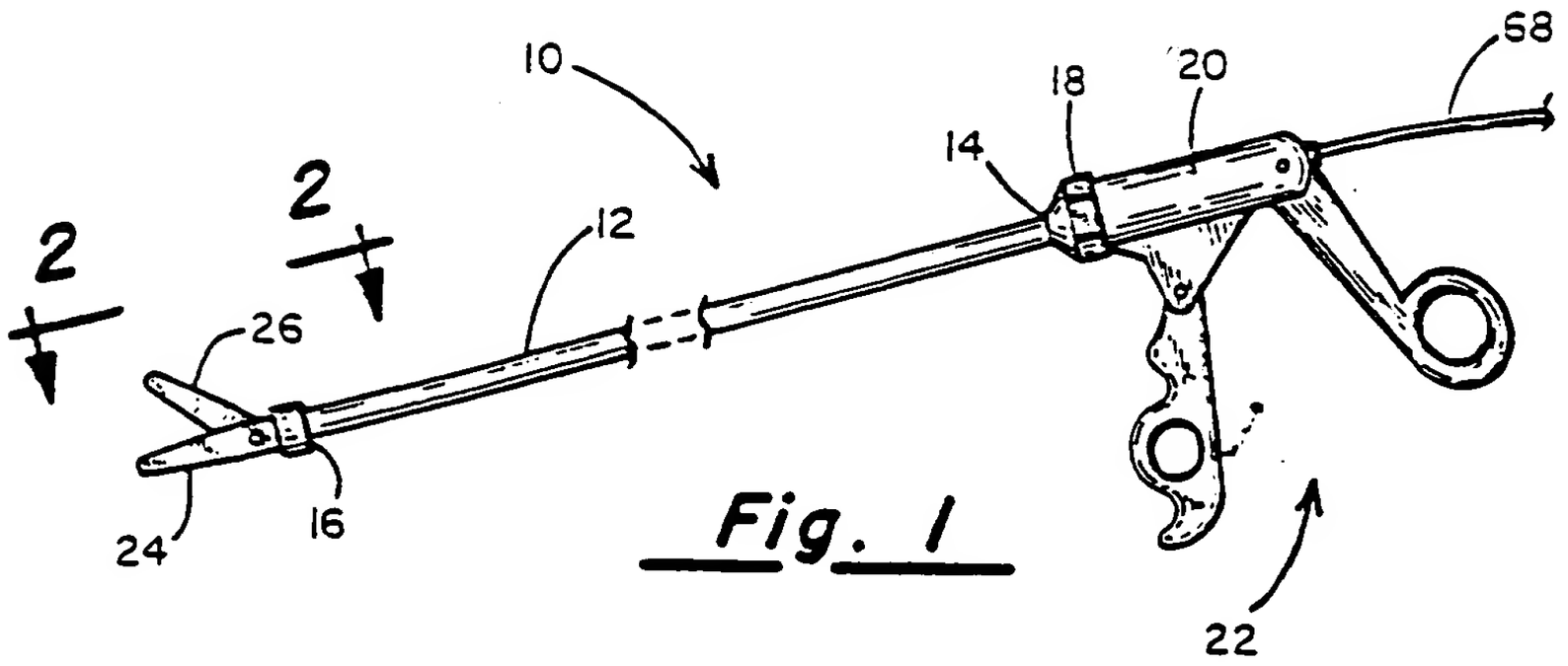

10
2
2
2
12
26
24
16
18
20
14
68
22

Fig. 1

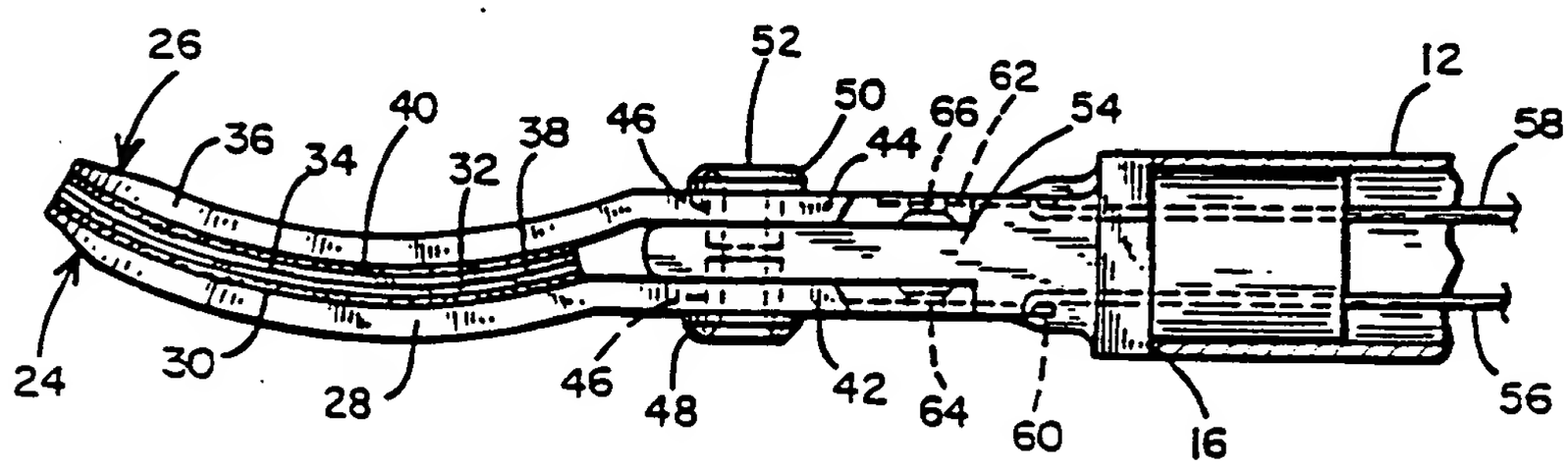

26
36
34
40
32
38
46
52
50
62
66
54
44
12
58
24
30
28
46
48
42
64
60
16
56

Fig. 2

SURGICAL SCISSORS WITH BIPOLAR COAGULATION FEATURE

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates generally to the design of a bipolar electrosurgical scissors, and more particularly to a surgical scissors incorporating bipolar electrodes as its blade elements, such that mechanical cutting with subsequent electrocoagulation can be achieved without requiring an instrument exchange.

2. Discussion of the Prior Art

Electrocoagulating instruments include at least one conductive electrode. Radio frequency energy is conducted through this electrode to either a remote conductive body-plate (monopolar) or to a second, closely-spaced conductive electrode (bipolar). Current passing through the gap between the two electrodes will coagulate blood and other body fluids placed between them.

Monopolar electrocautery instruments suffer from the fact that the return path between the active-electrode and the large area body-plate can be unpredictable as the electrical current seeks the return electrode through the path of least resistance. With bipolar electrosurgical instruments, however, because the two electrodes are closely spaced to one another, usually at the distal end of an instrument handle, the return path is very short and only involves the tissue and fluids in the short path between the electrodes.

There is available in the prior art a scissors-type instrument for mechanically snipping tissue during the course of an endoscopic procedure. Such a scissors comprises of pair of blades fabricated from metal and disposed at the distal end of an elongated tubular member whose outside diameter is sufficiently small to allow it to be passed through the working lumen of an endoscope, a laparoscope or other similar devices known in the art. Disposed at the proximal end of the rigid tube is a scissors-type handle having a pair of members, each with a finger-receiving loop therein which are pivotally coupled to one another. An appropriate linkage is made between the handle members and the blades so that manipulation of the handle members will result in an opening and closing of the blades relative to one another. When using a mechanical cutting scissors of this type to excise tissue, when a blood vessel is cut, bleeding results. At that point, it is generally necessary for the surgeon to remove the scissors instrument from the working lumen of the endoscope and then insert an electrocoagulator down the endoscope to the site of the bleeder. This instrument exchange is time-consuming and in a surgical procedure where moments count, it would be desirable to have a scissors-type instrument for cutting but which also incorporates the ability to coagulate blood and other body tissue using RF energy.

There is also available in the prior art monopolar scissors where both of the scissors blades form one pole and with a remote body plate being the second pole. To date, however, there is not available in the marketplace a bipolar electrosurgical scissors where its two blades are electrically isolated from one another and comprise the bipolar electrode pair. With metal-to-metal contact along the sharpened edges of the two blades, an electrical short results. Furthermore, the attempt to use a rivet or screw as the pivot point for the blades is another area where short-circuiting is likely to occur. When such a short exists, the electrical current does not flow through the blood or body tissue to effect coagulation, but instead, follows the short-circuit path from one electrode to the other.

In a copending application, Ser. No. 07/887,212, filed May 26, 1992, there is described a bipolar scissors for insertion into a laparoscope, trocar or endoscope for effecting electrocoagulation of blood and tissue during laparoscopic or other endoscopic surgery. The scissors blades at the distal tip of the instrument perform cutting of the tissue by mechanical shearing action. The two blades are effectively insulated from one another, allowing them to function as bipolar electrodes for electrocoagulating small blood vessels in the surgical field.

The instrument of the aforereferenced application includes a scissors-type handle having first and second pivoting members, each with a finger-receiving loop on one end of each and extending from the opposite end of one is an elongated, rigid tubular member of a size capable of being inserted through the trocar or endoscope. Affixed to the distal end of the rigid tubular member is a first blade composite which comprises a metal blank having a suitable ceramic layer bonded to one major surface thereof, the ceramic being honed to define a sharp cutting edge. Pivotally joined to the first blade by an insulating pivot member is a second blade composite, also having a metal blank with a ceramic substrate bonded to one major surface thereof. When the two blade blanks are pivotally joined together, the ceramic layers are in face-to-face relationship and because the cutting edges thereof are honed, the blades are capable of cutting tissue when made to move in a scissors-like manner with tissue placed between the cutting edges thereof.

Extending through the lumen of the elongated tubular member is a wire or rod which is rigid in the longitudinal direction and which is coupled at its proximal end to one of the handle members and at its other end to one of the scissors blades. By appropriately manipulating the handle members, a snipping action of the blades results.

The instrument further includes means for applying a RF voltage across the gap between the two metal blade blanks which are maintained separated from one another by the ceramic faces bonded to these blanks. As such, the blades of the instrument itself can be used as a bipolar electrocoagulation device, obviating the need for doing an instrument exchange when it is necessary to coagulate blood and tissue following the mechanical cutting thereof.

In copending application Ser. No. 08/092,076, filed Jul. 16, 1993, there is described a bipolar electrosurgical scissors having curved blades in the embodiments of each of the aforereferenced applications, the bipolar blades are constructed by appropriately adhering a specially ground ceramic insulating member defining the sheering surface and cutting edge of the scissors to metal electrodes where it is the ceramic surfaces that interact with one another to perform the cutting function as the blades are opened and closed relative to one another. While that arrangement works well in implementing a bipolar electrosurgical scissors, the cost of manufacture is relatively high because of the difficulty in working with ceramics, especially when constructing electrosurgical scissors having arcuate blades. Those skilled in the art appreciate that ceramic will readily fracture when subjected to bending forces and, hence, it

is necessary to produce the requisite ceramic elements for the scissors in a series of grinding operations.

A need therefore exists for a bipolar electrosurgical scissors for use in both open and endoscopic surgical procedures where the shearing surfaces may be surgical steel, but where the blades can also be used in performing bipolar electrocoagulation as the cutting progresses.

SUMMARY OF THE INVENTION

It is accordingly a principal object of the present invention to provide a bipolar, electrocoagulating instrument having metal scissors blades for the mechanical cutting of tissue.

Another object of the present invention is to provide a pair of bipolar scissors having a miniaturized distal blade configuration that allows the instrument to be inserted through a laparoscope, trocar or the working lumen of an endoscope.

Still another object of the present invention is to provide a bipolar-type scissors instrument having metal (stainless steel) cutting surfaces and which utilizes a push rod and pivot combination to cause movement of the scissors blade through manipulation of a scissors-style handle mechanism at the proximal end of the instrument and wherein blade supports for the scissors may be simultaneously energized from a RF source to effect the electrocoagulation of cut tissue.

The foregoing object of the invention is achieved by providing an instrument having a metal blade member with a sheering surface and a honed cutting edge. The blade member is affixed to a metal blade support by an electrically insulating bonding layer which is disposed intermediate the blade member and the blade support. In forming an endoscopic scissors, this blade assembly is pivotally secured to the distal end of an elongated tube. An actuating link extends through the tube to a movable portion of a scissors handle so that when the handle is manipulated, the blades can be made to open and close relative to one another in scissors-like fashion. Also extending through the lumen from electrical terminals on the handle to the metal blade supports are conductors which permit a voltage to be applied between the two blade supports. Because the blade having the sharpened edge and shearing surface is insulated from its blade support, there will be no short circuit between the blade members due to the fact that the conductive shearing surfaces come into contact with one another along their length as the blades are closed on an object to be cut.

It has been found convenient in the manufacture of the scissors of the present invention to employ a partially cured epoxy, an epoxy impregnated fiberglass mat or a slurry of glass beads and epoxy as the bonding layer for joining the blades to their respective supports while maintaining a desired spacing thereberween. The partially cured epoxy can be die-cut to size so as to conform in shape to the interface between the blade support and the blade member. When the laminated structure is clamped together and then subjected to a heating operation, the epoxy spacer layer fully cures and creates a strong bond between the blade and its blade support, while still maintaining electrical isolation therebetween.

DESCRIPTION OF THE DRAWINGS

The foregoing features, objects and advantages of the invention will become apparent to those skilled in the art from the following detailed description of a preferred embodiment, especially when considered in conjunction with the accompanying drawings in which like numerals in the several views refer to corresponding parts.

FIG. 1 is a perspective view of an endoscopic electrosurgical scissors constructed in accordance with the present invention; and

FIG. 2 is a greatly enlarged top view of the distal end portion of the scissors of FIG. 1.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to FIG. 1, there is indicated generally by numeral 10 a bipolar electrosurgical scissors for endoscopic surgery constructed in accordance with the present invention. It is seen to include an elongated tubular barrel 12 having a proximal end 14, a distal end 16 and with a lumen extending therebetween. The O.D. of the barrel is sufficiently small to be passed through the working lumen of an endoscope (laparoscope). Affixed to the proximal end 14 of the bipolar scissors 10 is a rotatable knob 18 appropriately mounted in the stationary portion 20 of a scissors handle assembly 22 so that the knob 18 can be rotated, the barrel 12 turning with it. Those desiring further details on the construction and internal workings of the handle assembly 22 are referred to applicant's earlier patent application Ser. No. 08/013,352, filed Feb. 5, 1993. That application describes in detail how manipulation of the scissors handle 22 causes blades 24 and 26 connected to the distal end 16 of the tube 12 to move in scissors-like action relative to one another. Because the novel features of the present invention center on the construction of the blades 24 and 26, there is no need to further describe the details of the handle construction.

Referring to FIG. 2, there is shown a greatly enlarged top plan view of the distal end portion of the scissors viewed along the line 2—2 in FIG. 1. Blade 24 is seen to comprise a conductive metal blade support 28, preferably fabricated from stainless steel. While the blade support 28 is illustrated as having an arcuate profile when observed from the top as in FIG. 2, it can just as well be straight. Attached to the blade support by means of a dielectric bonding agent 30 is a metal blade 32 having an arcuate shearing surface 34 and a honed cutting edge.

In adhering the cutting blade 34 to the blade support 28, it has been found convenient to employ a suitable epoxy, such as AF 125 sold by the 3M Company because of its desired dielectric characteristics. The epoxy bonding/spacing layer 30 may be obtained in a partially cured state so that it is rigid enough to hold its own shape, but can easily be die-cut to a desired size and shape characteristic. The partially cured epoxy layer is then applied against the concave surface of the blade support 28 and because in the partially cured state, the material is tacky, it will adhere to it. Next, the blade 34, itself, is pressed against the other side of the partially cured epoxy bonding layer 30 and when appropriately aligned, a suitable clamp is used to hold the assembly together. The assembly may then be placed in an oven or otherwise heated to the point where the epoxy layer becomes fully cured and hard. When the assembly is removed from the oven and the clamp is removed, it is found that a very strong bond holds the blade 34 to the support 28. The two are electrically insulated from one another, however, by the epoxy bonding layer.

To ensure that clamping and heating does not alter the width of the insulating gap, a fiberglass mat of the

drawings in which like
fer to corresponding

n er opic electro-
accordance with the

view of the distal end

PREFERRED
T

dicated generally by
cal scissors for endo-
rdance with the pres-
an elongated tubular
4, a distal end 16 and
een. The O.D. of the
passed through the
aparoscope). Affixed
olar scissors 10 is a
ounted in the station-
assembly 22 so that
el 12 turning with it.
he construction and
mbly 22 are referred
plication Ser. No.
hat application de-
of the scissors handle
d to the distal end 16
ke action relative to
tures of the present
on of the blades 24
escribe the details of

how greatly en-
end portion of the
in FIG. 1. Blade 24
tal blade support 28,
ss steel. While the
ving an arcuate pro-
n FIG. 2, it can just
e blade support by
30 is a metal blade
ace 34 and a honed

o the blade support
employ a suitable
3M Company be-
teristics. The epoxy
tained in a partially
gh to hold its own
a desired size and
ured epoxy layer is
rface of the blade
lly cured state, the
Next, the blade 34,
ide of the partially
when appropriately
hold the assembly
placed in an oven
ere the epoxy layer
en the assembly is
no is removed, it is
the blade 34 to the
ins d from one
iding layer.
ting does not alter
ergiass mat of the

desired thickness can be impregnated with a B-stage type epoxy or glass beads of a diameter corresponding to the desired gap width can be mixed with the B-stage epoxy before it is interposed between the blade and its support and prior to the clamping and heat curing thereof.

The other scissors blade 26 is manufactured in much the same fashion. It includes a blade support 36 and a blade member 38 bonded together by a dielectric bonding/spacing layer 40. The dielectric bonding/spacing layer is again preferably an epoxy or a glass-filled epoxy material adhered to the convex surface of the blade support 36.

The proximal end portions 42 and 44 of the blade supports 28 and 36 each have a circular aperture extending therethrough as at 46 and fitted into each of the apertures is an insulating bushing half 48–50 allowing a steel rivet 52 to pivotally secure the blades 24 and 26 to an insulating hub 54 without creating an electrical short circuit between the blade supports 28 and 36. The hub member 54 fits within the distal end 16 of the tubular barrel 12 and is appropriately bonded or swagged so as not to come loose.

The mechanism for actuating the blades 24 and 26 in a scissors-like motion is similar to that described in applicant's earlier copending application Ser. No. 08/013,352, which is herein incorporated by reference. In that arrangement, first and second conductive rods 56 and 58 extend through the lumen of the barrel 12 from the scissors handle members to a pair of conductive links 60 and 62. The links are pivotally secured to the distal ends of the rods 58 and 60 and to the blade halves 24 and 26 by means of conductive metal rivets 64 and 66. The rivets 64 and 66 pass through apertures formed in the distal end portions of the blade halves 24 and 26 at locations that are off of center so that a lever arm is created for moving the blades as the conductive rods 56 and 58 are reciprocally, longitudinally displaced by actuation of the scissors handle 22. A slip-ring connection is provided in the handle portion 20 for allowing conductors in the insulated electrical cord 68 (FIG. 1) to join to the conductive rods 56 and 58 while still permitting the barrel 12 to be rotated upon turning the knob 18 and without twisting the conductors in lead 68. In this fashion, a predetermined RF voltage may be applied across the blade supports 28 and 36 by way of the lead 68, the conductive rods 56 and 58, the links 60 and 62 and the rivets 64 and 66. Because of the insulating layers 30 and 40 used in bonding the sharpened blades 32 and 38 to the blade supports 28 and 36, those two blades can touch one another along their entire length as the cutting motion takes place without creating an electrical short circuit thereberween. When it is desired to cauterize tissue, the RF voltage is applied to the electrosurgical scissors, thereby making the blade supports the active bipolar electrodes. When the two blade supports are brought into contact with tissue, a current flows from the first blade support, through the tissue to the second blade support, thereby effecting cauterization.

The present invention obviates the need for providing a somewhat fragile ceramic layer to define the shearing surface and cutting edges of the blades. The stainless steel blade supports and the blades themselves can be readily bent to create a curved blade without the need for expensive grinding operations heretofore necessary in creating curved ceramic pieces.

The use of a partially cured epoxy dielectric adhesive in the early stages of fabrication for adhering the blade to its support and then later fully curing the epoxy layer also greatly simplifies the steps needed to manufacture an electrosurgical scissors having bipolar electrodes.

This invention has been described herein in considerable detail in order to comply with the Patent Statutes and to provide those skilled in the art with the information needed to apply the novel principles and to construct and use such specialized components as are required. However, it is to be understood that the invention can be carried out by specifically different equipment and devices, and that various modifications, both as to the equipment details and operating procedures, can be accomplished without departing from the scope of the invention itself. For example, while an endoscopic scissors has been used in explaining the invention, it is equally applicable to a scissors designed for open surgery. Hence, the scope of the invention is to be determined from the appended claims.

What is claimed is:

1. A bipolar electrosurgical instrument for cutting and coagulating tissue comprising:

(a) first and second blade members each comprising a laminated assembly of a metal blade defining a shearing surface, a metal blade support and an intermediate electrically insulative bonding/spacing layer for joining said blade to said blade support;

(b) means for pivotally joining said first and second blade members together with their respective shearing surfaces facing one another;

(c) means coupled to at least one of said first and second blade members for imparting a scissors-like movement relative to the other of said first and second blade members; and

(d) means for applying a voltage between the metal blade supports of said first and second blade members.

2. The bipolar electrosurgical instrument as in claim 1 wherein said shearing surfaces of said first and second blade members and said blade support are curved.

3. The bipolar electrosurgical instrument as in claim 2 wherein said intermediate, electrically insulating bonding/spacing layer is an epoxy material.

4. The bipolar electrosurgical instrument as in claim 3 wherein said epoxy material includes a fiberglass-mat of a predetermined thickness therein.

5. The bipolar electrosurgical instrument as in claim 3 wherein said epoxy material includes glass microspheres of a predetermined maximum diameter therein.

6. The bipolar electrosurgical instrument as in claim 3 wherein said metal is stainless steel.

7. A bipolar electrosurgical instrument for cutting and coagulating tissue comprising, in combination:

(a) an elongated tubular member having a proximal end, a distal end and a lumen extending therebetween;

(b) first and second blade members, each comprising a laminated assembly of a metal blade defining a shearing surface, a metal blade support and an intermediate electrically insulating spacing/bonding layer for joining said blade to said blade support;

(c) means for pivotally joining said first and second blade members to the distal end of said elongated tubular member with their respective shearing surfaces facing one another;

(d) a handle affixed to said proximal end of said tubular member;

(e) means coupled to said handle and extending through said lumen for imparting a scissors-like movement to at least one of said first and second blade members relative to the other; and

(f) means extending through said lumen for applying a voltage between said blade supports of said first and second blade members.

8. The bipolar electrosurgical instrument as in claim 7 wherein said intermediate electronically insulating bonding layer is an epoxy material.

9. The bipolar electrosurgical instrument as in claim 8 wherein said epoxy material includes a fiberglass-mat of a predetermined thickness therein.

10. The bipolar electrosurgical instrument as in claim 8 wherein said epoxy material includes glass microspheres of a predetermined maximum diameter therein.

11. The bipolar electrosurgical instrument as in claim 7 wherein said first and second blade members are curved.

* * * * *

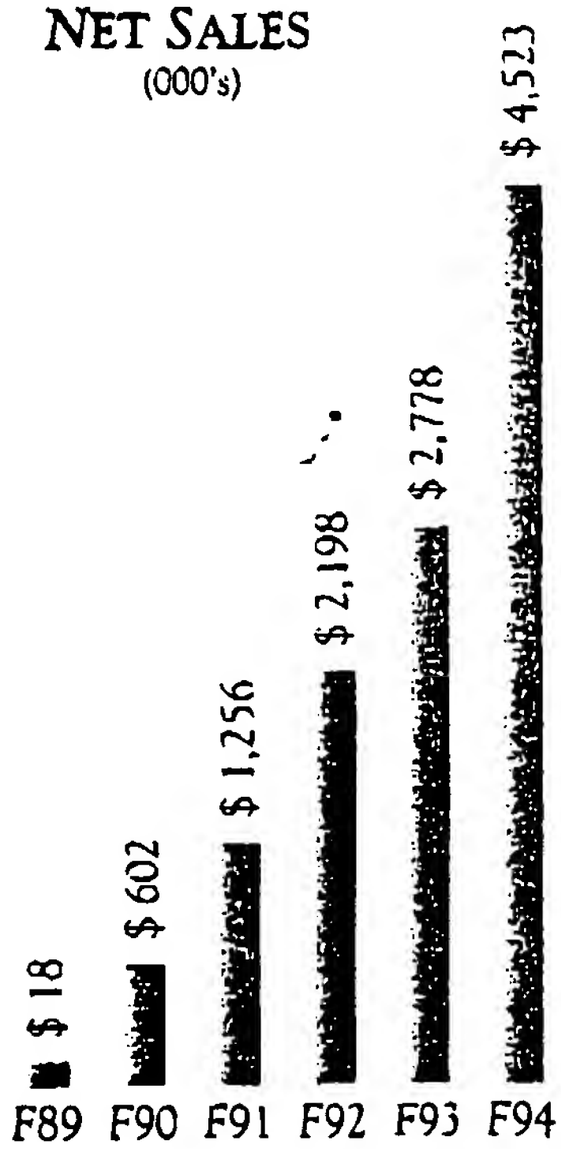
Exhibit 6

IMPROVED FINANCIAL RESULTS

In fiscal 1994, revenues increased 63 percent to $4,523,295 from $2,778,834 in the prior year. The net loss for the fiscal year was $788,335, or $.17 per share, a significant reduction from $2,997,847, or $.57 per share, in 1993. The fourth quarter sales included a favorable pricing adjustment from an OEM customer resulting in the largest revenue quarter in the Company's history and its first profitable quarter. Sales for this quarter were $1,219,638, an increase of 45 percent over 1993, with net income of $6,657 versus a net loss of $368,134 in the prior year.

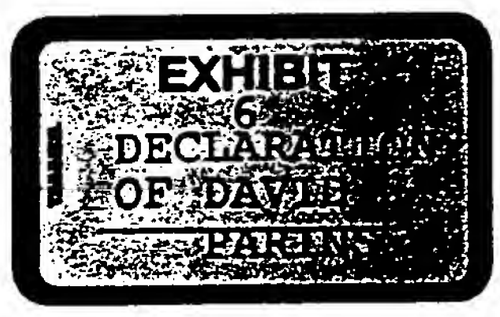
Revenues for all market segments experienced growth during the year. Our line of EVERSHEARS® Bipolar Scissors well exceeded $1,000,000 in sales for the year. Our OEM laparoscopy business contributed significantly to our sales growth, albeit significantly below expectations. Sales of the bipolar polypectomy snare to Japan more than doubled for the fiscal year. In addition, our shipments of the bipolar coagulating probe to C.R. Bard were strong in the second half of the year.

NET SALES
(000's)



We continued our prudent control of operating expenses for the year. These actions coupled with productivity gains enhanced the Company's gross margin, better leveraged the operating structure and resulted in a significant reduction in the prior year's loss.

To assist our sales growth, the Company raised $1,100,000 in equity capital through a private placement in August.



A SUPERIOR TECHNOLOGY FOR A GROWING MARKET

Minimally Invasive Surgery (MIS) continues to represent a clear technological advancement that contributes to improved patient outcomes, while reducing health care delivery costs and other related expenditures. The conversion rate to minimally invasive procedures from open procedures continues to increase.
It is projected that 95 percent of gall bladder removals and 40 percent of hysterectomies will be performed laparoscopically by 1997. New advanced laparoscopic procedures, such as spinal implants, nissan fundaplications and vagotomies — surgical procedures to improve digestion — are gaining acceptance. Many experts believe that minimally invasive surgery will become the primary modality for surgical intervention by the year 2000.

Inherently safer bipolar electrosurgery is gaining recognition and acceptance in the growing MIS market which currently relies on monopolar energy. The use of monopolar energy increases the risk of patient injuries due to unintended thermal injury and lateral tissue damage. The use of bipolar electrosurgery virtually eliminates these dangers. Bipolar energy offers the surgeon more control and less tissue damage with effective hemostasis and uncompromised performance. In addition, many surgeons find the use of bipolar electrosurgery may save surgical time, as well as the expense associated with sealing vessels mechanically.

As surgical procedures become more complex in anatomically-crowded areas of the body, the need for the safety of bipolar energy becomes increasingly appealing to patients, clinicians and administrators.

The acceptance of bipolar electrosurgical instrumentation continues to build as evidenced by other medical device companies' interest in this category. Ethicon Endo-Surgery, a division of Johnson & Johnson, and Cabot Medical Corporation have recently announced major new bipolar product offerings to the market with others considering entry.

We believe this bodes well for Everest Medical as these larger, better-financed marketers assist in increasing the awareness and credibility of bipolar energy, thus increasing the size of this market segment.

INNOVATIVE NEW PRODUCTS

In the third quarter of 1994, the Company introduced three innovative new products for the laparoscopic market — the EVERSHEARS II Bipolar Metal-on-Metal Curved Scissors, the BiCOAG® Bipolar Dissecting Forceps and the BiLAP® Bipolar Needle Electrode. The EVERSHEARS I Ceramic Bipolar Scissors was the first bipolar scissors available for general sale throughout the world. The second generation EVERSHEARS II Bipolar Scissors incorporates a patented design that improves the reliability, precision and performance of the product with improved gross margin potential. In addition, this design significantly improves the clinical *feel* over our first generation ceramic product. The BiCOAG Dissecting Forceps is an unique, versatile instrument that allows the surgeon to grasp and dissect tissue, and to coagulate with the safety of bipolar energy. The BiLAP Needle Electrode is a precision cutting device that provides outstanding cutting performance with improved safety. All of these devices are priced competitively and are compatible with most common electrosurgical generators.

For the first time in the Company's history, the Everest Medical distribution channel has a full line of bipolar instrumentation to offer to safety-conscious clinicians.

During 1994, the Company's status relative to its bipolar scissors intellectual property became clearer. The Company learned the U.S. Patent Office issued two patents to another company involving ceramic scissors technology in 1994. In October 1994, the Company received a patent on its second generation EVERSHEARS II metal-on-metal design. After review of the allowed claims of these patents and the patent files, the Company, based on advice of counsel, believes that its metal-on-metal design does not infringe either of these two patents. The Company commenced full market introduction of the metal-on-metal design in January 1995.

Fiscal 1994 was a year of re-commitment to the Everest Medical independent distribution channel. We believe that this network of quality distributors and independent marketing representatives will be the most important factor in increasing our market share. The Company has significantly upgraded its domestic sales force; nearly sixty percent of the sales force has been replaced during the past twelve months. We have been successful in attracting high quality sales organizations who share our vision for bipolar technology. Currently, the Company has over 70 independent sales professionals representing Everest-branded bipolar products domestically with a primary emphasis in gynecology and general surgery. Our strategic focus will be to concentrate our resources on the Everest Medical independent sales professionals to better leverage our expanding product offerings.

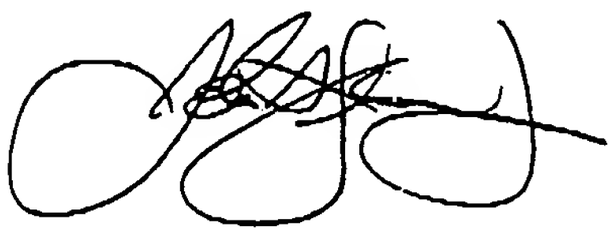
THE FUTURE

Everest Medical is the world's leader in bipolar electrosurgery technology and uniquely positioned to take advantage of the MIS market's movement to this safer modality. It is our belief that bipolar technology will become the standard in electrosurgery in all minimally invasive surgery markets.

To ensure our continued participation and success in this opportunity, the Company has assembled an outstanding core of technical excellence to provide innovative, superior bipolar instrumentation. Given our recent financial progress, we believe that we have stabilized the Company. We can now become more aggressive with investments in product development and sales efforts to meet our long-term financial goals.

We look forward with optimism to fiscal 1995. Our intent is to attain profitability by year-end and be in a position to sustain profitability thereafter.

We would like to specifically acknowledge the efforts of Everest Medical employees for their contribution to our success. To our shareholders, we thank you for your continued support.



John L. Shannon Jr.
President and Chief Executive Officer

David D. Koentopf
Chairman of the Board of Directors